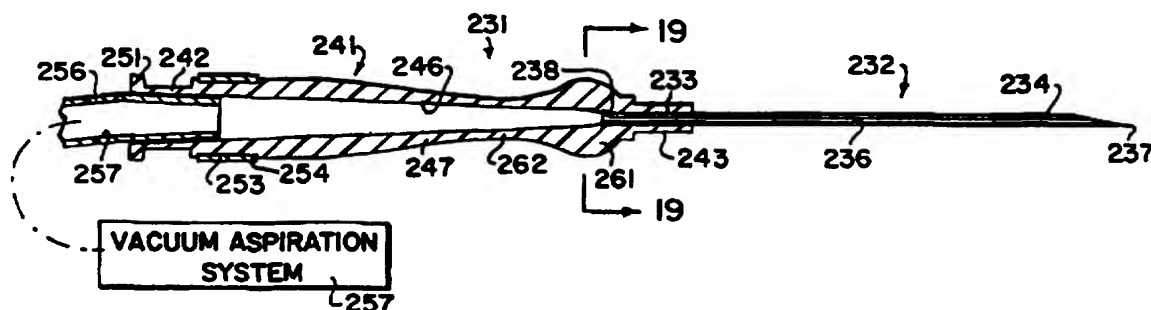




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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| <b>(51) International Patent Classification <sup>6</sup> :</b><br><b>A61M 5/00, 5/31</b>  | <b>A1</b> | <b>(11) International Publication Number:</b> <b>WO 96/32146</b><br><b>(43) International Publication Date:</b> 17 October 1996 (17.10.96)   |
| <b>(21) International Application Number:</b> PCT/US96/04271<br><b>(22) International Filing Date:</b> 28 March 1996 (28.03.96)<br><b>(30) Priority Data:</b><br>08/421,063                      13 April 1995 (13.04.95)                      US<br><b>(71) Applicant:</b> ADVANCED CYTOMETRIX, INC. [US/US]; 995 Benecia Avenue, Sunnyvale, CA 94086 (US).<br><b>(72) Inventors:</b> POWLES, Trevor, J.; Greenhedges, Coulsdon Lane, Chipstead, Surrey CR5 3QP (GB). IMRAN, Mir, A.; 741 Barron Avenue, Palo Alto, CA 94036 (US). GANDHI, Deepak; 911 Bowen Avenue, San Jose, CA 95123 (US). SYED, Baber, R.; 3445 Kenneth Drive, Palo Alto, CA 94303 (US).<br><b>(74) Agents:</b> HOHBACH, Harold, C. et al.; Flehr, Hohbach, Test, Albritton & Herbert, Suite 3400, Four Embarcadero Center, San Francisco, CA 94111-4187 (US). |           | <b>(81) Designated States:</b> AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).<br><br><b>Published</b><br><i>With international search report.</i> |

**(54) Title:** ASPIRATION NEEDLE AND METHOD**(57) Abstract**

This invention is an aspiration needle (231) for use in collecting large cell samples with a source of vacuum for fine needle aspiration cytology without increasing the size of the needle having a rigid elongate tubular member (232) having distal (234) and proximal extremities (233). The tubular member has a bore (236) extending therethrough from the distal extremity to the proximal extremity, and has an opening at the distal extremity in communication with the bore. A body (241) is secured to the proximal extremity of the tubular member and forms a chamber (246) therein in communication with and in close proximity to the opening into the bore of the tubular member. The chamber is formed by a sloping uninterrupted wall (247) leading distally to the opening to the bore of the tubular member. The body includes a hub (251) proximal of the chamber for receiving the source of vacuum and for establishing communication between the source of vacuum and the chamber.

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### ASPIRATION NEEDLE AND METHOD

This invention relates to an aspiration needle and method for use in fine needle aspiration cytology.

5 Fine needle aspiration cytology has heretofore been utilized as a standard technique for the diagnosis of cancer utilizing a standard 23 gauge intravenous needle attached to a standard 10 milliliter syringe. In such a technique, the intravenous needle is passed through the skin into the tumor. The barrel of the syringe is withdrawn 3 or  
10 4 milliliters while attached to the needle as the needle is passed three or four times through the tumor. This procedure sucks up a small amount of tissue fluid together with loose cells into the needle with some concurrent spillage up into the nozzle of the syringe. The needle is  
15 then removed from the tumor and detached from the syringe. Air is then drawn up into the syringe. The needle is reattached and the small amount of fluid with cells therein in the needle is forced out of the needle by operation of the syringe and blown onto a microscopic slide. The small  
20 amount of fluid is then smeared against another slide to produce a film on both slides which is then air dried and appropriately stained. Typically an accurate analysis of the lump can be made from a microscopic examination of these slides by an expert. In such a procedure it has been found  
25 that with a standard 23 gauge needle, the volume of the needle is often exceeded by the aspirate so that the sample passes up into the socket of the needle connected to the syringe and is partly entrapped therein preventing expression

of the sample onto the slide. Also, it has been found that in many cases, the sample so obtained is inadequate to provide a clear diagnosis. Furthermore, newly developed immunocytochemical techniques for detecting proteins in cells can be used on cytological preparations for predicting growth characteristics, prognosis and likely response to treatment. These techniques require larger numbers of cells, than are currently obtained using standard aspiration equipment. Utilizing such standard intravenous needles, it has only been possible to obtain something in the order of 5,000-10,000 cells which is only adequate for cytodiagnoses in about 60-70% of the patients. There is therefore need for a new and improved aspiration needle which will make it possible to obtain larger cell samples without increasing the external size of the needle. In addition, it has been found that the syringes utilized with such aspiration needles have been difficult to use during such aspiration procedures. There is therefore also a need for a new and improved syringe for use with the improved aspiration needle.

In general, it is an object of the present invention to provide an aspiration needle and method for use in fine needle aspiration cytology.

Another object of the invention is to provide an aspiration needle of the above character which is provided with a transparent spherical lens portion surrounding a portion of the conical chamber to permit viewing of the contents of the distal extremity of the conical chamber.

Another object of the invention is to provide an aspiration needle of the above character which is provided with the capability of accommodating a vibrator at the proximal extremity of the body of the aspiration needle.

Another object of the invention is to provide an aspiration needle of the above character in which the lens portion provides a magnification of the proximal extremity of the chamber to facilitate viewing of the sample as it is being aspirated into the chamber.

Another object of the invention is to provide an aspiration needle of the above character in which first and second hubs are provided and in which a fluid chamber is provided in the distal hub and a sample collection chamber is provided in the proximal hub.

Another object of the invention is to provide an aspiration needle of the above character in which the proximal and distal hubs are substantially of the same configuration.

Additional objects and features of the invention will appear from the following description in which the preferred embodiments are set forth in detail in conjunction with the accompanying drawings.

FIG. 18 is a side elevational view in section of an aspiration needle incorporating the present invention having a single lumen therein.

FIG. 19 is a cross-sectional view taken along the line 19-19 of FIG. 18.

FIG. 20 is a cross-sectional view of an aspiration needle similar to that shown in FIG. 18 but having a vibrator attached to the proximal extremity of the aspiration needle.

FIG. 21 is a cross-sectional view of another embodiment of an aspiration needle incorporating the present invention which is comprised of proximal and distal hubs and proximal and distal chambers with the distal chamber containing a liquid and the proximal chamber serving as a collection chamber.

In general, the aspiration needle incorporating the present invention for fine needle aspiration cytology is comprised of a rigid elongate tubular member having distal and proximal extremities. The distal extremity is formed to provide a sharp point. The tubular member has a bore extending therethrough from the distal extremity to the proximal extremity. A body is secured to the proximal extremity of the tubular member and forms a conical chamber which is in communication with the bore of the tubular member. The chamber is formed by a sloping continuous

uninterrupted side wall leading to the bore of the tubular member. The chamber is formed by a sloping uninterrupted side wall leading distally to the opening to the bore of the tubular member. The body is provided with a generally spherical portion surrounding the distal extremity of the chamber to provide a magnification of the distal extremity of the chamber. The body includes a hub separate from the chamber based proximally of the chamber for receiving a source of vacuum and for establishing communication between the source of vacuum and the chamber.

A single lumen aspiration needle 231 incorporating the present invention is shown in Figures 18 and 19. As shown therein the single lumen aspiration needle 231 consists of a tubular member or cannula 232 which is provided with proximal and distal extremities 233 and 234 and has a large centrally disposed lumen 236 extending from the proximal extremity to the distal extremity. The tubular member 232 is provided with a centrally disposed lumen 236 extending from the proximal extremity to the distal extremity. The interior surface of the tubular member 232 forming the lumen 236 can be polished so as not to traumatize cells as they are aspirated as hereinafter described. The distal extremity 234 is provided with a sharpened tip 237 that is formed by a bevel provided on the distal extremity. The proximal extremity 233 is slightly flared outwardly to provide a flare 238 having no sharp edges. The tubular member cannula 232 can be of a suitable size as for example 23 gauge having an outside diameter of .025" and an inside diameter ranging from .018 to .020" to provide the desired column strength for the tubular member 232.

An elongate body 241 formed of a suitable transparent material such as ULTEM is mounted on the proximal extremity 233 of the tubular member 232 and by way of example can be molded thereon. The elongate body 241 can have a suitable length as for example 1.90" and is provided with a proximal extremity 242 and a distal extremity 243. The distal extremity 243 has the proximal extremity 233 of the tubular

member 232 disposed therein with the flared distal end 234 having the funnel-shaped recess 238 therein opening into an elongate conical chamber 246 which extends through the proximal extremity 242. The conical chamber 246 is formed  
5 by an uninterrupted wall 247 which is provided with a small taper extending in a substantially straight line as for example at an angle ranging from 3° to 6° and preferably approximately 4° as shown with respect to a central axis of the body 241. The wall 247 has a smooth surface and  
10 provides an uninterrupted transition into the conical recess 238 of the tubular member 232. The proximal extremity 242 is provided with a hub or fitting 251 which can be in the form of a luer type fitting.

A metal ring 253 formed of a suitable ferro-magnetic  
15 material is mounted in an annular recess 254 on the outer surface of the proximal extremity 242 of the body 241. A flexible tube 256 which is provided with a lumen 257 extending therethrough and is mounted by a slip fit in the proximal extremity of the chamber 246 and is connected to  
20 a vacuum aspiration system 257 of a type hereinbefore described. The system 257 can be utilized for applying a steady vacuum or a pulsating vacuum in a manner hereinbefore described to the chamber 246. The body 241 is provided with an enlarged spherical portion 261 on its distal extremity  
25 which surrounds the distal extremity of the conical chamber 246 in a region immediately adjacent the flared end of the tubular member 232. This spherical portion serves as a convex lens which provides magnification of the interior of the conical chamber so as to make it possible to readily  
30 envision when aspirate is drawn through the tubular member 232 into the conical chamber 246. Although the body 241 has an exterior surface which is generally cylindrical, it is provided with an annular depression immediately proximal of the spherical portion 241 which is adapted to be grasped  
35 by two fingers of the hand as for example the thumb and forefinger to facilitate insertion and withdrawal of the aspiration needle 231 in the manner hereinbefore described.

The conical chamber 246 can be of a suitable size as for example from 0.075 milliliters to 0.15 milliliters and preferably approximately 0.1 milliliters. The conical chamber 246 has a highly polished sloping surface which is uninterrupted and leads into the funnel-shaped recess 238 provided at the proximal extremity of the tubular member 232.

Operation and use of the single lumen needle is very similar to the needles hereinbefore described. The needle can be readily grasped by having two fingers of the hand grasp the annular recess 262 in the body 241 to direct the needle 231 through the skin of the patient and to direct the needle into a palpable tumor. As soon as the needle has penetrated the tumor, a negative pressure or vacuum can be created by use of the vacuum aspiration system 251 as hereinbefore described to create a subambient condition within the chamber 246 to cause aspirate to be withdrawn from the tumor into the bore 236 and into the chamber 246. As soon as aspirate enters the chamber 246 it can be visually observed by the magnifying portion 261 and at the same time to observe how much aspirate is being collected in the chamber 246. After sufficient aspirate has been withdrawn, the aspirate can be utilized in the manner hereinbefore described. Alternatively, the aspirate can be retained as a specimen within the chamber and if necessary an appropriate medium added to preserve the specimen. A cap (not shown) can be placed on the distal extremity 234 of the tubular member 232 and a cap (not shown) over the fitting 251 and then transporting the same to a laboratory for analysis. This eliminates the necessity of making slides along the bedside of the patient.

In Figure 20, the same aspiration needle 231 as hereinbefore described in Figures 18 and 19 is shown in which a vibrator 266 is disposed over the proximal extremity of the body 241 and overlies the metal ring 253. The vibrator 266 is connected to a power supply 267 which supplies a pulsating current to the vibrator which causes vibratory



motion in a direction longitudinal of the central axis of the aspiration needle 231. The vibrator 266 can be of the type hereinbefore described and creates a pulsating magnetic field which is translated into longitudinal mechanical motion of the needle 231 to cause the tip of the needle 237 to vibrate longitudinally from a few tenths of a millimeter to several hundred microns. As hereinbefore explained previously, this facilitates the collection of cells and aspiration of the same into the lumen 236 of the aspiration needle while a negative pressure is being created within the chamber 236 as for example by means of a conventional syringe 271.

Another aspiration needle incorporating the present invention is shown in Figure 21. The aspiration needle shown therein is in the form of a dual lumen aspiration needle assembly 281 which consists of at least two single lumen aspiration needles 231 of the type hereinbefore described that are mounted in tandem with the distal extremity 243 of the body 242 being mounted by slip fit within the hub for a fitting 251 of the distal single lumen aspiration needle 231. The tubular member 232 of the second single lumen aspiration needle 231 is of a length so it extends through the conical chamber 246 of the first single lumen aspiration needle 231 and extends into the funnel-shaped recess 238 of the tubular member of the first single lumen aspiration needle as shown in Figure 21.

In accordance with the present invention, if desired, the tubular member 232 can be of a larger size to accommodate the needle of the other single lumen aspiration needle 231 as shown in Figure 21 to form a fluid-tight seal therewith with such an arrangement it can be seen that there are provided two conically-shaped chambers 246 with the first chamber 246 in the distal needle 231 serving for example as a fluid chamber and the conical chamber 246 in the proximal needle 231 serving as a sample collection chamber. In this way it can be seen that a dual chamber needle can be created by merely putting one needle inside the other

as for example a smaller needle within a larger needle. Magnification is provided for both chambers in both locations. Thus a suitable fluid such as a cell culture medium can be placed in the first chamber whereas the  
5 aspirate can be collected in the sample chamber by placing a vacuum or a pulsating vacuum on the chamber 246 of the proximal needle 231.

From the foregoing it can be seen there have been provided additional single and dual lumen aspiration needles  
10 incorporating the present invention which have additional advantageous features for the collection of aspirate. The collection of aspirate can be viewed under magnification so that the collection process can be carefully observed.

WHAT IS CLAIMED IS:

1. An aspiration needle for use in collecting large  
cell samples with a source of vacuum for fine needle  
5 aspiration cytology without increasing the size of the needle  
comprising a rigid elongate tubular member having distal  
and proximal extremities, the tubular member having a bore  
extending therethrough from the distal extremity to the  
proximal extremity and having an opening at the distal  
10 extremity in communication with the bore and a body secured  
to the proximal extremity of the tubular member and forming  
a chamber therein in communication with and in close  
proximity to the opening to the bore of the tubular member,  
said chamber being formed by a sloping uninterrupted wall  
15 leading distally to the opening to the bore of the tubular  
member, said body including a hub proximal of the chamber  
for receiving said source of vacuum and for establishing  
communication between the source of vacuum and the chamber,  
said body having an enlarged portion adjacent the proximal  
20 extremity of the tubular member permitting viewing of the  
chamber in the vicinity of the proximal extremity of the  
tubular member to facilitate observation of aspirate as it  
is collected in the chamber.

2. A needle as in Claim 1 wherein said enlarged  
25 portion encircles said chamber.

3. A needle as in Claim 1 wherein said collection  
chamber is conical and is formed by an inclined uninterrupted  
conical wall extending in a substantially straight line.

4. A needle as in Claim 3 wherein the body has a  
30 central axis and wherein said conical wall extends at an  
angle of approximately 3° to 6° with respect to the central  
axis of the body.

5. A needle as in Claim 1 further including a ring  
formed of a ferro-magnetic material carried by the proximal  
35 extremity of the body.

6. A needle as in Claim 5 further including a vibrator disposed on the needle and overlying at least a portion of the metal ring.

5 7. A needle as in Claim 1 together with an additional needle of the same type as the first named needle and having its tubular member extending through the conical chamber of the first named needle and extending into the tubular member of the first named needle to form a fluid-tight fit therewith.

10 8. In a dual lumen aspiration needle assembly for use in collecting cell samples with a source of vacuum, first and second aspiration needles mounted in tandem with the second aspiration needle being mounted proximally of the first aspiration needle, each of said first and second  
15 aspiration needles including a body having a chamber therein and a tubular member carried by the body and having a bore therein in communication with the chamber, the tubular member of the second aspiration needle extending through the bore of the first aspiration needle and extending into the tubular  
20 member of the first aspiration needle, said body of the second aspiration needle having means for making a connection with the chamber of the first aspiration needle.

9. An aspiration needle as in Claim 8 together with magnification means carried by the body of each of the first  
25 and second needles for magnifying the interiors of the chambers of the first and second needles.

10. A method for performing fine needle aspiration cytology in a tissue of the body by the use of a fine aspiration needle having a lumen therein, introducing the  
30 needle into the tissue and applying a pulsating vacuum to the lumen to facilitate aspirating cells from the tissue.

11. A method as in Claim 10 wherein the fine aspiration needle is provided with an additional lumen together with the step of supplying a liquid medium through the additional  
35 lumen to cause the liquid medium to flow into contact with the cells to aid in collecting cells for aspiration through the first lumen.

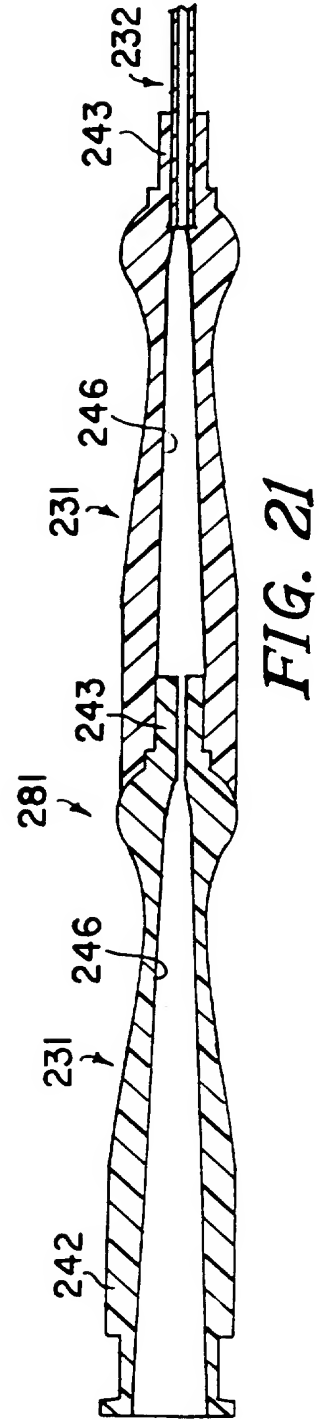
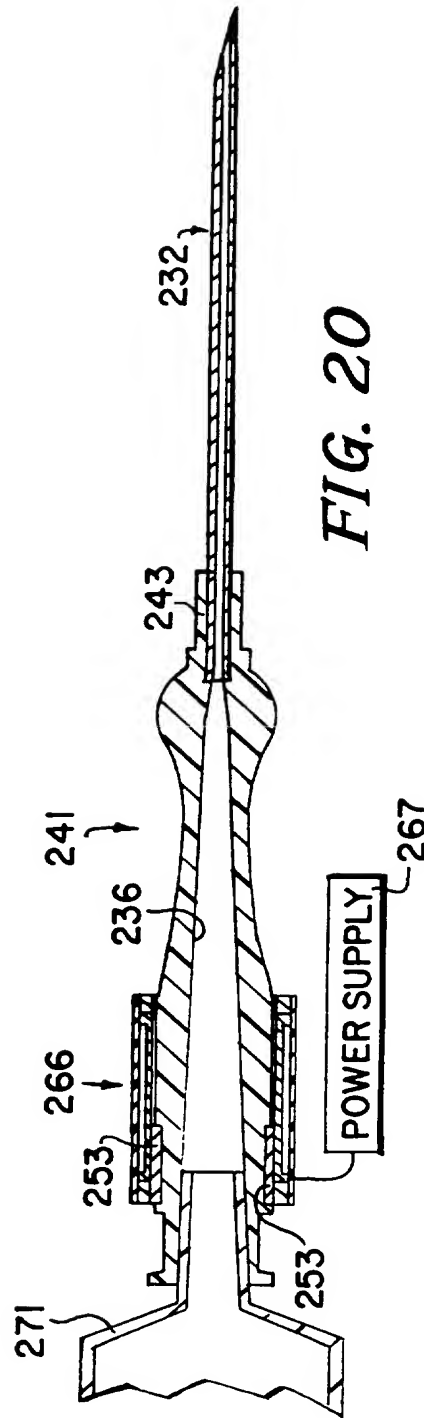
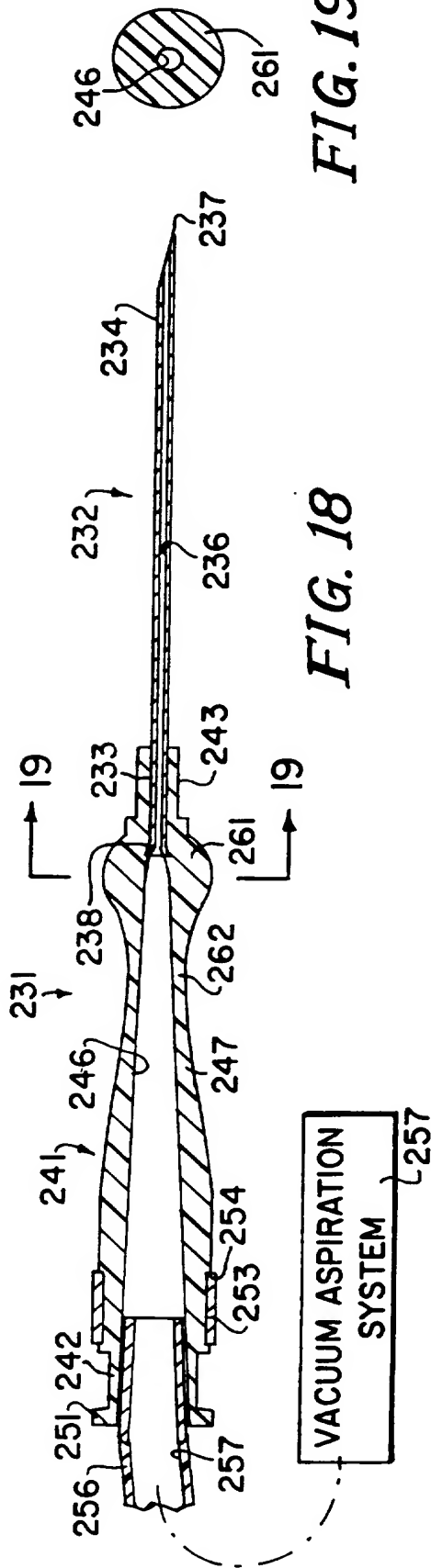
12. A method as in Claim 11 wherein a saline solution is supplied through the additional lumen.

13. A method for fine needle aspiration cytology by the use of a fine aspiration lumen having a lumen therein,  
5 supplying mechanical vibratory motion to the lumen to collect cells from the tissue and supplying vibrating forces to the needle during the time that cells are being collected from the tissue.

14. A method as in Claim 13 wherein the vibratory  
10 motion is provided in a direction longitudinal of the axis of the needle and wherein the vibratory motion is provided during introduction of the needle into the tissue to facilitate introduction of the needle into the tissue.

15. A method as in Claim 13 wherein the vacuum supplied  
15 to the lumen is a pulsating vacuum.

16. A method as in Claim 13 wherein the fine aspiration  
needle is provided with an additional lumen together with the steps of and supplying a liquid medium to the additional lumen to aid in aspirating cells from the tissue.



# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US96/04271

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61M 5/00. 31

US CL : 604/240

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/763, 765, 741, 770; 604/22, 51, 168, 187, 140, 141, 147, 239, 240, 243, 247, 264 272-274.

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category*        | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------------|--|-----------------------|
| A<br>---<br>X/ Y | US, A, 4,737,150 (BAEUMLE ET AL.) 12 April 1988, see entire document.              | 7<br>-----<br>8/ 9    |
| A<br>---<br>Y    | US, A, 5,030,207 (MERSCH ET AL.) 09 July 1991, see entire document.                | 1-4<br>-----<br>9     |
| P,A              | US, A, 5,494,044 (SUNDBERG) 27 February 1996, see entire document.                 | 1-16                  |
| A                | US, A, 4,425,115 (WUCHINICH) 10 January 1984. See entire document.                 | 1-16                  |

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Further documents are listed in the continuation of Box C.

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See patent family annex.

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Date of the actual completion of the international search

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